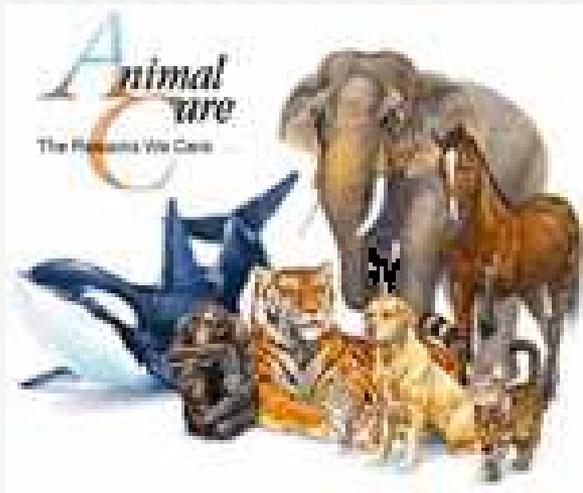


Rulemaking by APHIS

This slide show is intended only to give an overview of the USDA/APHIS rulemaking process. Please note that the rulemaking process is modified from time to time. Please do not rely on this slide show as the only source of information.





The rulemaking process

Proposed Rule

What is a rule and when must APHIS conduct rulemaking?

- Under U.S. law, a rule is any requirement of general applicability and future effect
- An agency may issue rules only within the scope of its authorizing legislation
- APHIS must conduct rulemaking whenever it wishes to enforce a rule

What is the rulemaking process?

- The principal requirements for rulemaking are set by the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.)

(Continued)

What is the rulemaking process?

For most rulemaking, the APA requires:

- Publication of a proposed rule in the Federal Register
- Opportunity for the public to submit written comments
- Publication in the Federal Register of a final rule, with an explanation of any changes that the agency has made and a response to the public comments
- An effective date for the final rule that is at least 30 days after publication, unless the rule relieves restrictions or there is other good cause for making the rule effective earlier

(Continued)

What is the rulemaking process?

Publication in the Federal Register:

- Provides official notice to the public of a document's existence and content
- Indicates the document was properly issued
- Provides evidence that is judicially noted by a court of law
- Rules that are not properly issued may be successfully challenged in court

Proposed Rule

Identify Need:

- Internal or external sources (such as petition -- 7 CFR 1.28)
- Risk Analyses if needed

Prepare a Workplan:

- Review by RAD
- OMB designates whether significant, not significant, economically significant

Draft Proposed Rule for Federal Register:

- All required analyses and impact statements completed
- OGC and other USDA Offices Reviews Proposed Rule
- For significant, or economically significant, OMB reviews
- Each reviewer may send it back for corrections, questions, or comments
- If changed, must send back through OGC

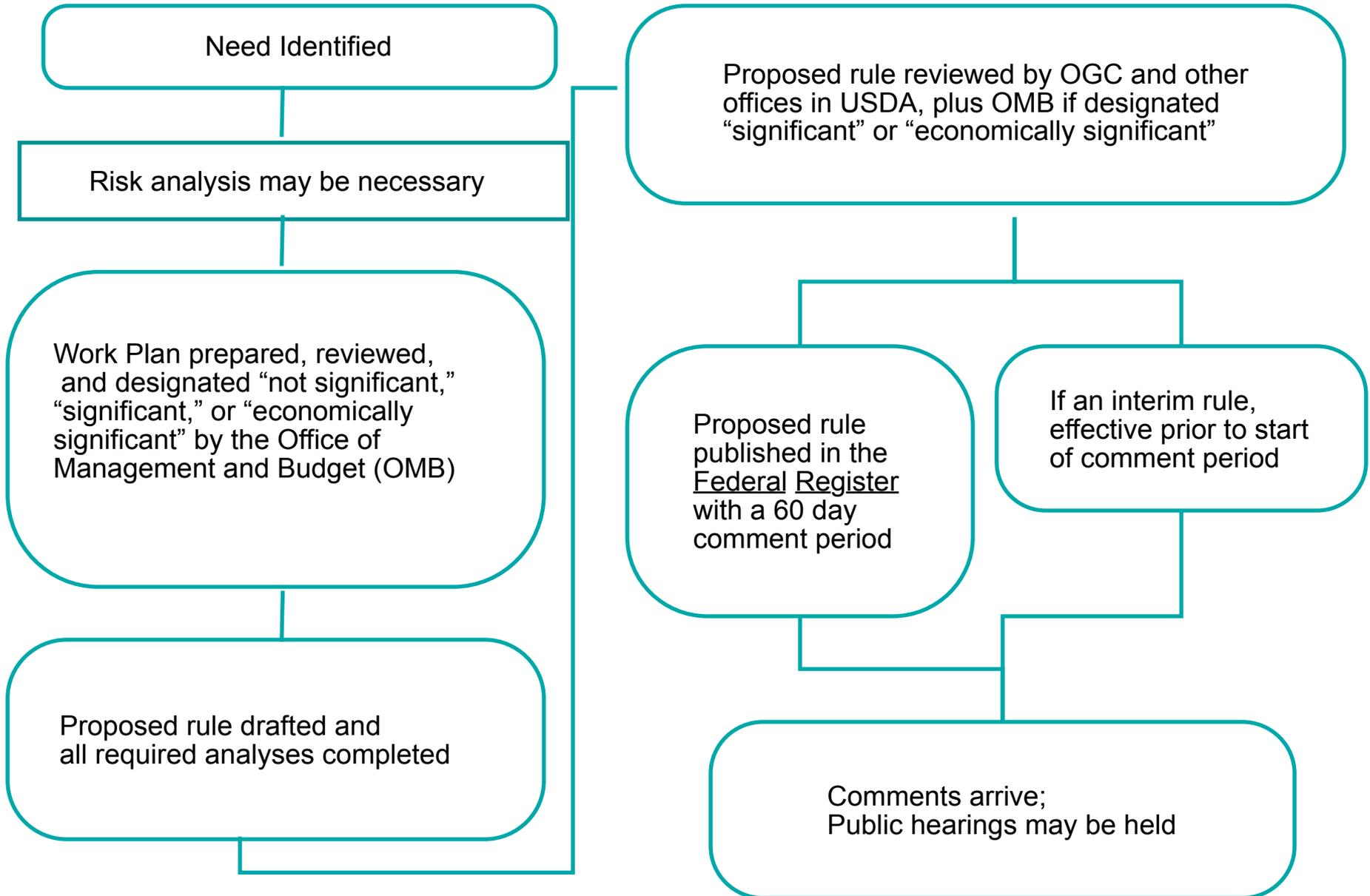
After agency review is completed:

- Proposed Rule with usually a 60 day comment period or
- Interim rule effective prior to and during the comment period
- Publish in Federal Register

Comments Received by Agency Officials:

- Public Hearings may be held at this point
- Comments are reviewed and answer prepared
- Make decision as to future of proposed rule

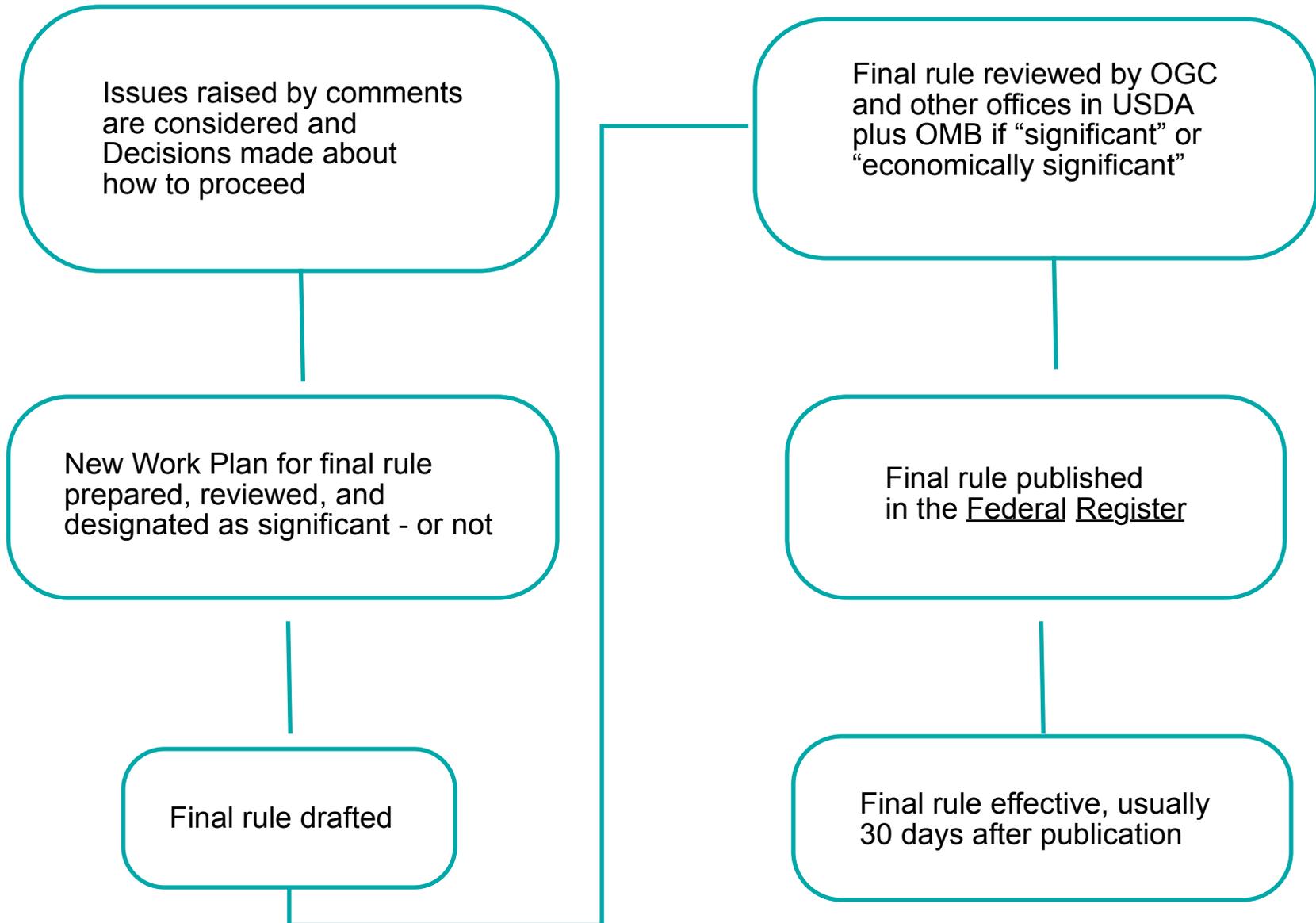
Proposed Rule



Final Rule

- Comments Reviewed
 - Issues raised by comments are considered
 - Decision made on how to proceed with proposed rule
 - Leave as is
 - Amend
 - Cancel
- Final Rule Workplan
 - Prepared and designated as significant -- or not
- Final Rule Drafted
- Agency review repeated (OGC, OMB, and other offices)
- Final Rule Published in Federal Register
- Final Rule usually becomes effective 30 days or more after publication
- Interim rules are already in place but may be modified by final rule

Final Rule



Designations

- Not significant
- Significant
- Economically significant

Non-significant:

This term has nothing to do with an action's importance or priority; it simply means that OMB has decided not to review the docket.

Significant:

An action that is likely to:

- Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a section of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Economically significant:

An action likely have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a section of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

How long does this process take?

Time depends on:

- Complexity of rule
- Number and nature of comments received
- Priority assigned by the Agency (APHIS has an average of 150-200 actions in progress at any given time)
- For example: BSE rules and actions have the priority at this time
- The designation assigned by OMB

Continued

How long does this process take?

“Significant” and “economically significant” rules take longer because:

- More analyses are required and those analyses are usually fairly detailed
- The clearance process is longer

Non-Significant vs Significant Clearance

“Not significant” rules:

- OGC
- Deputy Administrator
- Administrator
- Office of Budget and Program Analysis (OBPA)
- Under Secretary, Marketing and Regulatory Programs
- Administrator to sign
- Published in Federal Register

“Significant” rules:

blue text items are additional clearances

- OGC
- Deputy Administrator
- Administrator
- The General Counsel for USDA
- OBPA
- Office of the Chief Economist
 - Plus the Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) for economically significant rules
- Assistant Secretary for Administration
- Office of the Chief Information Officer
- Under Secretary for Marketing and Regulatory Programs
- Secretary
- OBPA
- OMB
- Under Secretary to sign
- Published in Federal Register

Typical Time Required for Rulemaking

Not significant:

- 1 year or more

Significant:

- 2-3 years or more

Note: Almost all of Animal Care's Rules are designated as significant

What is the basis for all of the steps?

- The Administrative Procedure Act (APA) sets forth only the basic requirements for rulemaking
- However, there are a number of other laws and Presidential executive orders that also must be followed

(continued)

Executive Order 12866 of Sept. 30, 1993, “Regulatory Planning and Review”

- Requires agencies to notify OMB of all intended regulatory actions
- Provides for OMB review of actions designated “significant” and “economically significant”
- Requires agencies to assess the costs and benefits of rules and issue rules only when the benefits outweigh the costs

(Continued)

Executive Order 12866 of Sept. 30, 1993, “Regulatory Planning and Review”

- Requires a public comment period of at least 60 days in most cases
- Requires agencies to consult with officials of State, local, and tribal governments
- Requires agencies to base regulations on the best reasonably available scientific, economic, technical, and other information

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Requires agencies to assess the potential economic effects of rules on small U.S. businesses, nonprofit organizations, and small governmental jurisdictions

The National Environmental Policy Act (42 U.S.C. 4321 et seq.)

Requires agencies to evaluate the potential environmental consequences of proposed actions in a forum open to the public

The Paperwork Reduction Act of 1995 (U.S.C. 3501 et seq.)

Requires agencies to obtain approval from OMB before collecting information from the public or requiring the public to keep records

The Congressional Review Act of 1996 (5 U.S.C. 801 et seq.)

- Requires agencies to submit all interim rules and final rules to Congress before the scheduled effective dates of the rules
- Requires a waiting period of 60 days after publication before a “major” (“economically significant”) rule may take effect, except in an emergency situation

Section 7 of the Endangered Species Act (16 U.S.C. 1536)

Requires agencies to consult with the Fish and Wildlife Service of the U.S. Department of the Interior before taking any action which could threaten any endangered species of animal or plant

The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

Principles of:

- Transparency
- Harmonization
- Equivalence
- Risk assessment
- Regionalization

End of Rulemaking Presentation

